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EXAMINER	
KRYLOVA, IRINA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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Attachment to Advisory Action

1. The amendment filed by Applicant on December 13, 2010 has been fully considered. Exhibits A and B filed by Applicant are considered. The amendment is entered. In light of the amendment, arguments and Exhibits A and B filed by Applicant on December 13, 2010, claim objections and the rejection of claims 1-3, 5-9, 21 under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516) in view of **Seth et al** (US 4,721,709) are withdrawn, thus rendering Applicant's argument moot. All other rejections are maintained.

2. Regarding the rejections of claims 1-3, 5-9, 21 under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516) in view of **Haynes et al** (US 5,660,857) and claims 1, 3-9, 21 under 35 U.S.C. 103(a) as being unpatentable over **Gregory et al** (US 4,371,516) in view of **Haynes et al** (US 5,660,857), **Gole et al** (US 5,648,093), **Unger et al** (US 5,502,082) and **Fujimoto** (JP 01011141), Applicant argues that:

a) with respect to **Gregory et al,** one of ordinary skill in the art would have not been motivated to include the co-solvent that would lead to formation of an emulsion when mixed with the aqueous solution of the polymeric material; the only mentioned co-solvents are water-miscible alcohols which would not form an emulsion;

b) Examples provided in **Gregory et al** recite lorazepam or other drugs that not formed into emulsion;

c) "oil-in-water emulsion formed" lattice cannot be considered as product by process limitation as it gives different porous structure;

d) **Haynes et al** discloses composites that are prepared by mixing protein, an oleaginous material (oil) and water to form an emulsion with subsequent drying the emulsion to remove water only and contains significant quantities of an oleaginous material held within the matrix itself; the emulsion is freeze dried to form a sponge; thus the composite of **Haynes et al** would not have pores formed from sublimation of the oil phase of the emulsion; **Haynes et al** does not disclose creating porous bodies that are water soluble.

3. Examiner disagrees.

Gregory et al discloses shaped articles having a porous open matrix network of water-soluble or water-dispersible carrier (col. 2, lines 37-40), the articles carrying a chemical and capable of being rapidly disintegrated by water (col. 1, lines 58-64), wherein the article comprise:

A) a polysaccharide, polyvinyl alcohol, polyvinyl pyrrolidone or mixtures thereof;

B) a surfactant, such as polyoxyethylene sorbitan monooleate (col. 4, lines 5-8).

The surfactant prevents the freeze dried product from sticking to the surface of the mold and also aids in the dispersion of the chemical (col. 4, lines 1-7).

The porous bodies of **Gregory et al** are used for delivering both hydrophilic, such as lorazepam, and hydrophobic, such as clonazepam, drugs. Further, **Gregory et al** clearly teaches the use of a co-solvent to improve solubility of the chemical, i.e. drug

(col. 3, line 68-col. 4, line 2). Since hydrophobic drugs are soluble in hydrophobic solvents, i.e. oily solvents, therefore, it would have been obvious to a skilled artisan to use as an oil-based co-solvent that will improve the solubility of hydrophobic drug clonazepam, in the process of **Gregory et al** as well. Though not explicitly recited by **Gregory et al**, however, combination of water, oily-based co-solvent and a surfactant (col. 4, lines 1-7) appears to produce oil-in-water emulsion as well since hydrophobic water-insoluble drug will be solubilized in the internal oily phase, thereby remaining in the preferred solution state. Further, it is noted that the oil phase (and preparation of oil-in-water emulsion) disclosed in the instant invention is used for the same purpose as that of **Gregory et al**, i.e. to improve solubility of hydrophobic materials (see p. 4, lines 28-34 of the instant invention).

Though the Examples provided in **Gregory et al** do not disclose the use of oily co-solvents and thus do not show the formation of oil-in-water emulsion, however, this does not negate a finding of obviousness under 35 USC 103 since a preferred embodiment such as an example is not controlling. Rather, all disclosures "including unpreferred embodiments" must be considered. In re Lamberti 192 USPQ 278, 280 (CCPA 1976) citing In re Mills 176 USPQ 196 (CCPA 1972). Furthermore, the exemplified drugs, such as lorazepam, are hydrophilic and thus are soluble in water.

2) Further, **Haynes et al** discloses a process for preparing a composite comprising preparing an oil-in-water-emulsion followed by freeze drying the emulsion (col. 2, lines 40-42) to form a sponge (col. 2, lines 30-31). The oil phase is used for dissolving oestradiol hydrophobic drug (col. 4, lines 34-36; col. 2, lines 50-51). Thus, **Haynes et al**

clearly teaches the use of oily phase to solubilize the hydrophobic phase and thus, forming an oil-in-water emulsion in the presence of water and a surfactant, followed by freeze drying the emulsion. This procedure results in the formation of sponge (as cited in col. 2, lines 41-44). By definition, "sponge" is a porous material. Therefore, by freeze drying the oil-in-water emulsion comprising a hydrophobic drug, at least partially porous material will be formed. Furthermore, US 4,837,285, incorporated by reference in **Haynes et al** (col. 4, lines 50-54), recites the beads produced by freezing the emulsion as microporous beads. Therefore, the sponge of **Haynes et al** appears to be microporous as well. Furthermore, **Haynes et al** does not specify that only water is removed during freeze drying. Though **Haynes et al** recites that significant quantities of an oleaginous material held within matrix, however, that does not mean that during freeze drying step oil phase will not sublimate at least partially to form pores. Though **Haynes et al** does not disclose creating porous bodies that are water soluble, however, **Haynes et al** is a secondary reference. Secondary reference does not need to teach all limitations. "It is not necessary to be able to bodily incorporate the secondary reference into the primary reference in order to make the combination." *In re Nievelt*, 179 USPQ 224 (CCPA 1973).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irina Krylova whose telephone number is (571)270-7349. The examiner can normally be reached on Monday-Friday 8:00am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasudevan Jagannathan can be reached on (571)272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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